DEC 2 3 2013

510(k) SUMMARY

PREPARATION DATE:	September 27, 2013
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 467-4007 Fax: (919) 467-3300
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical and Regulatory Affairs
DEVICE TRADE NAME:	LipiFlow® Thermal Pulsation System *Model LFTP-1000, Console and* *Model LFD-1000 & LFD-1100, Activator (Disposable)*
CLASSIFICATION NAME:	Eyelid Thermal Pulsation System
DEVICE CLASSIFICATION:	Class II; 21 CFR 886.5200
PRODUCT CODE:	ORZ
PREDICATE DEVICE:	LipiFlow® Thermal Pulsation System *Model LFH-1000, Handheld Control System and* *Model LFD-1000, Disposable* Cleared under K093937and Evaluation of Automatic Class III Designation on June 28, 2011 *Model LFTP-1000, Console and* *Model LFD-1000, Activator (Disposable)* Class II under 21 CFR 886.5200 Applicant: TearScience, Inc. Cleared under K112704 on December 19, 2011 (corrected letter received January 12, 2012) Class II under 21 CFR 886.5200 Applicant: TearScience, Inc

DEVICE DESCRIPTION:

The LipiFlow® Thermal Pulsation System is used by a physician in an in-office procedure for patients with chronic cystic conditions of the eyelids to provide controlled heat to the inner eyelid surface, close to the location of the meibomian glands, and intermittent pressure to the outer eyelid to facilitate release of lipid from the cystic meibomian glands. The LipiFlow® System is comprised of a physician interface (Control

component) and a patient interface (Disposable component). The Console (Control component) provides the electrical power, user interface, treatment monitoring, treatment control and safeguard circuitry used for controlling the heat and pressure applied to the patient's eyelids by the Activators (Disposable component). No changes to the Console are proposed in this 510(k).

The Activator (Disposable) is a sterile, single-use, biocompatible eyepiece made of polycarbonate and silicone and is inserted around the patient's eyelids. The Activator (Disposable) consists of a combined eye cup and lid warmer with attached tubing and wiring that connect to the Console with a connector. There are two models of the Activator (Disposable). Except for the addition of a memory device, Activator (Disposable) Models LFD-1000 (cleared under K093937) and LFD-1100 (modified under design controls) are equivalent with no difference in device performance, safety or effectiveness.

This 510(k) submission is for a device modification of new materials for the LipiFlow® Activator (Disposable). The proposed changes to the Activator (Disposable) are to provide a second source for the raw materials used in the eyecup bladder (diaphragm), lid warmer glue and heater components to facilitate manufacturing. The model numbers of the Activator (Disposable) will not change as a result of this change. The LipiFlow® Activator (Disposable) with the new second source materials has the same intended use and same fundamental scientific technology as the predicate cleared device (LipiFlow® Activator (Disposable) with cleared materials, as described in K093937 and K112704). Accordingly, this 510(k) submission for a design change to use second source new materials in the Activator (Disposable) applies to both model numbers (LFD-1000 and LFD-1100) of the Disposable component.

INTENDED USE:

The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye. The Intended Use has not changed.

TECHNOLOGICAL CHARACTERISTICS:

Similarities: The new second source materials used in the fabrication of the Activator (Disposable) were selected based on their similarities in material properties including biocompatibility. The Activator (Disposable) fabricated with the new second source materials employs the same principle of operation to provide the same heat and pressure therapy to the eyelids. The Activator (Disposable) fabricated with the new second source materials is visually indistinguishable from the predicate device. The safety features incorporated in the existing Console and Activator (Disposable) configurations have not changed.

Differences: The patient contact biocompatible silicone material used to fabricate the bladder component of the Activator (Disposable) has changed to new second source

biocompatible silicone materials. The new materials are self-bonding to the plastic substrate. The existing cleared materials require a bonding agent to be applied to the substrate prior to molding. The patient contact biocompatible UV-cured cyanoacrylate adhesive has changed to a lower viscosity version, allowing the adhesive to more readily be used in conjunction with automated equipment. The electrically conductive plastic used to fabricate the heater within the lid warmer has been second sourced from another plastic manufacturer.

PERFORMANCE TESTING:

Performance testing demonstrated conformance to the *special controls* for an eyelid thermal pulsation system per 21 CFR 886.5200, which include:

1) Testing to validate EMC and safety of exposure to non-ionizing radiation.
2) Design, description, and performance data validating safeguards related to the temperature and pressure aspects of the device, including during fault conditions;
3) Performance data demonstrating the sterility of patient contacting components and the shelf-life of these components.
4) Performance data demonstrating biocompatibility of patient contact materials.
5) Performance data demonstrating that any technological changes do not adversely affect safety and effectiveness.

The LipiFlow® System with the Activator with new bladder, glue and heater materials passed all design verification and validation tests, including validation of the temperature and pressure performance and safeguards.

- The temperature and pressure safeguards related to the Activator operate as designed and are substantially equivalent between the new and original materials. The material changes in the Activator do not affect any of the temperature or pressure safeguards.

- The temperature and pressure performance of the Activator with new second source materials is substantially equivalent to the predicate Activator with original materials. The Activator with new materials meets the same design requirements as the Activator with existing materials based on known safe and effective temperature and pressure specifications, previously validated in bench, animal and clinical studies of the LipiFlow® System (refer to K093937 and K112704).

CONCLUSIONS:

Neither the Intended Use nor the Indications For Use have changed as a result of the proposed second-source materials. The proposed second-source materials for the Activator (Disposable) conform to all required special controls, are substantially equivalent to the cleared predicate device, do not raise new questions of safety and effectiveness, and do not adversely affect safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

TearScience, Inc.
% Christy Stevens, OD, MPH
Vice President, Clinical and Regulatory Affairs
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

Re: K133127
Trade/Device Name: LipiFlow® Thermal Pulsation System
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid thermal pulsation system
Regulatory Class: Class II
Product Code: ORZ
Dated: October 24, 2013
Received: October 28, 2013

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

LIPIFLOW® SYSTEM: NEW ACTIVATOR MATERIALS TRADITIONAL PREMARKET NOTIFICATION

INDICATIONS FOR USE

510(k) Number: K133127

Device Name: LipiFlow® Thermal Pulsation System

Model Numbers: LFTP-1000, LFD-1000 and LFD-1100

Indications For Use:

The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K133127